



K 072789

510(k) Summary

DATE: 5/19/07

510(k) Submitter:

ENCISION INC.
6797 Winchester Circle
Boulder, CO 80301 USA
Establishment Registration: 1722040

JUL 19 2007

Contact Person:

Judith V. King, VP Regulatory Affairs and Quality Assurance
Phone: 303-339-6917
Fax: 303-444-2693
e-mail: jking@encision.com

Device Name: AEM Disposable Electrodes and AEM Disposable Handpieces**Common name:** Device, Electrosurgical, Cutting and Coagulation and Accessories**Classification:** CFR Section: 878.4400**Class:** II**Product Code:** GEI**Predicate Devices:****Electrodes**

Trade, Proprietary or Model Name	Manufacturer
Model ES1000 series Monopolar Laparoscopic Electrodes with Electroshield	ENCISION INC.
Model 30-6000 series Reusable Monopolar Electrodes	Kirwin Surgical Products
Model 8380 series Unipolar Electrodes	Richard Wolf Medical Instruments Corp.
Models SW11100, SW11200, SW11202, SW11300 (Reusable) and SW1220, SW12202, SW12300 (Disposable) Electrosurgical Pencils	Shining World Healthcare Co., Ltd.

Handpieces

Trade, Proprietary or Model Name	Manufacturer
Model ES1000 series Monopolar Laparoscopic Electrodes with Electroshield	ENCISION INC.
Model ES4000 AEM Cord (AEM Monitor accessory)	ENCISION INC.
Model E2508 Disposable Pencil	Valleylab, Inc.
Models SW11100, SW11200, SW11202, SW11300 (Reusable) and SW1220, SW12202, SW12300 (Disposable) Electrosurgical Pencils	Shining World Healthcare Co., Ltd.

ENCISION®

Description of Devices:

The AEM Disposable Electrode and the AEM Disposable Handpiece connect to a compatible electrosurgical generator via an adapter on the ENCISION AEM Monitor. The handpiece has foot switching and hand switching versions. The electrodes and handpieces are single use products, which are provided sterile. They are designed not to be re-sterilized.

The AEM Monitoring System, including the electrodes and handpieces, are designed to minimize the likelihood of stray energy injuries caused by active insulation failure or capacitive coupling. The monitor does this by shutting down the ESU when excessive current is returned via the shield circuit which extends to near the tip of the electrode.

The electrodes, which consist of an insulated tip, shaft with locking knob, and AEM shield assembly, are available in various tip styles. The electrode has an inner insulation between the active conductor and shield tube, as well as a secondary outer insulation on the outside of the electrode shaft. The electrodes snap into the handpiece.

One version of the handpiece provides switching for the Cut and Coag functions of the ESU. This version has an integral cord. The other version uses foot-switching provided with the electrosurgical generator. The foot-switching handpiece connects to either the existing reusable or disposable AEM Cord from Encision. The electrodes may be removed from the handpiece and replaced with another electrode within the sterile field.

The electrode can rotate freely or be locked in one of multiple orientations relative to the handpiece, as preferred by the surgeon.

Intended Use:

AEM Disposable Electrodes and AEM Disposable Handpieces are electrosurgical accessories intended, by use of monopolar high-frequency electrical current from compatible electrosurgical generators, for ablation, removal, resection and coagulation of soft tissue where associated hemostasis is required in open, endoscopic and laparoscopic surgical procedures.

The devices are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

AEM instruments incorporate the use of AEM technology and are intended for use with the Encision AEM Monitoring System and electrosurgical generators having compatibility with the AEM Monitor.

Technological Characteristics:

The Encision AEM Disposable Electrodes and AEM Disposable Handpieces incorporate the same technological characteristics as the predicate devices for delivery of the ESU high frequency current, consisting of insulated conductors and shafts with appropriately shaped tips for electrosurgery. The control for ESU Cut and Coag modes on the handswitching handpiece is a switch similar in design and function to the predicate handpiece.

Like the Encision predicate devices, the AEM Disposable Electrodes and AEM Disposable Handpieces include an additional AEM shielding function which diverts stray energy from the shaft of the instrument and is monitored by the Encision AEM Monitor.

Non-clinical Performance Testing:

Performance of the devices' AEM technology and delivery of electrosurgical energy has been verified by bench testing consisting of continuity and capacitance measurements, and



compatibility testing with a worst case representative electrosurgical generator and the AEM Monitor.

Conclusions:

The AEM Disposable Electrodes and AEM Disposable Handpieces are safe and effective and are substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2007

Encision, Inc.
% Intertek Testing Services
Mr. Daniel W. Lehtonen
2307 East Aurora Road Unit B7
Twinsburg, Ohio 44087

Re: K072789

Trade/Device Name: AEM Disposable Electrodes and AEM Disposable Handpieces
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 28, 2007
Received: October 1, 2007

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

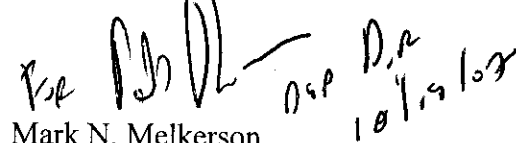
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Daniel W. Lehtonen

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a date '10/19/08' written to the right.

Mark N. Melkerson

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure



Indications for Use

510(k) Number (if known): K 072789

Device Name: AEM Disposable Electrodes and AEM Disposable Handpieces

Indications For Use:

The AEM Disposable Electrodes and AEM Disposable Handpieces are electrosurgical accessories intended, by use of monopolar high-frequency electrical current from compatible electrosurgical generators, for ablation, removal, resection and coagulation of soft tissue where associated hemostasis is required in open, endoscopic and laparoscopic surgical procedures.

The devices are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Prescription Use X
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

A handwritten signature in black ink, appearing to be "M. D. O.", written over a horizontal line.

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number 1672789